

REMARKS:

Applicant has carefully studied the Final Examiner's Action, the Advisory Action and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

Claim Rejection 35 U.S.C. 103(a)

Claims 1-4, and 8-14 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Eggers et al. (U.S. Patent No. 6,623,454) as modified by Eggers et al.

The Office states that Eggers et al. discloses in Fig. 19, a device comprising an elongated member comprising a cylindrical core electrode (118) surrounded by a first nonconductive insulator sleeve (108); a first electrode, and a second nonconductive sleeve being in independent circuit communications with a respective portion of a source of electrical energy, the electrodes begin fully capable of being able to establish an electromagnetic field in vivo to cause electromigration of molecules and transient permeability of cell membrane; and the device further having a portal (132) through which a substance may be passed. While the Office admits that Eggers et al. does not expressly disclose a second electrode member and a third nonconductive insulator sleeve, the Office concludes that at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to add an additional electrode and insulating layer because Applicant has not disclosed that having three electrodes and three insulating sleeves as opposed to two provides an advantage, is used for a particular purpose, or solves a stated problem. As such, the Office concludes that it would have been an obvious matter of design choice to modify Eggers et al. with an additional electrode and insulating layer to obtain the invention as specified in claims 1 and 12.

Independent claims 1 and 12 have been amended to more clearly describe that which the Applicant regards as the invention.

Amended independent claim 1 recites, “a device for manipulating a molecule *in vivo* relative to a target tissue comprising: a generally cylindrical nonconducting core post; at least three discrete electrodes, each of the at least three discrete electrodes being circumferential rings disposed to surround the nonconductive core post and each of the at least three electrodes positioned in axially spaced apart relation along the nonconducting core post, each electrode being in independent circuit communication with a respective portion of a source of electrical energy, the electrodes being configured to establish a first electromagnetic field *in vivo* between selected electrodes sufficient to cause electromigration of a molecule through the target tissue along the axial length of the core post between the selected electrodes and a second electromagnetic field sufficient to cause transient permeability of a cell membrane within the target tissue between the selected electrodes; and an insulating material interposed axially between the circumferential ring electrodes for achieving relative electromagnetic isolation of the electrodes”. As such, in accordance with the present invention, activation of selected electrodes which are positioned along the core post, cause electromigration of a molecule through the target tissue along the axial length of the core post. Therefore, the positioning of the electrodes along the core post allows for 3-dimensional manipulation of a molecule within the target tissue by activating opposing pairs of electrodes at different axial levels to induce molecular movement and/or electropermeabilization along a desired pathway.

The Office states in the Final Office Action mailed on November 11, 2008, “at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to add an additional electrode and insulating layer because Applicant has not disclosed that having three electrodes and three insulating sleeves as opposed to two provides an advantage, is used for a particular purpose, or solves a stated problem”. Additionally, the Office states in the Advisory Action, “Examiner disagrees and maintain her stance that a mere duplication of the essential working parts of a device involve only routine skill in the art (St. Regis Paper Co. v. Bemis Co., 193 USPQ 8)”. The Office also states that the Applicants themselves have stated in paragraph [0038] that “it can be appreciated by one of skill in the art that any number of electrodes and insulators could be successively configured in overlapping fashion to produce a multielectrode member tailored to a particular application”.

Applicant respectfully disagrees with this conclusion by the Office.

Applicant contends that it would not be an obvious matter of design choice to a person of ordinary skill in the art to add an additional electrode and insulating layer and it would not have been an obvious matter of design choice to modify Eggers et al. with an additional electrode and insulating layer to obtain the invention as specified in claim 1. Applicant contends that the Office has failed to consider the discovery of the problem for determining obviousness.

The CCPA has stated that, “It should not be necessary for this court to point out that a patentable invention may lie in the discovery of the source of a problem even though the remedy may be obvious once the source of the problem is identified. This is part of the “subject matter as a whole” which should always be considered in determining the obviousness of an invention under 35 U.S.C. 103 (*In re Nomiya*, 509 F. 2d 566, 184 USPQ 607, 612 (C.C.P.A. 1975)).

The Applicant states in the Background of the Invention regard the prior art in the field, “Electric fields are applied in only two dimensions of the three-dimensional tissue matrix. This limits the area of each cell that can be electroporated (FIG. 1), which reduces delivery efficiency.” As such, the Applicant has established that a problem exists in the prior art, wherein the prior art devices and methods are not capable of establishing a three-dimensional field within the three-dimensional tissue matrix for electromigration and electroporation. As such, Applicant has discovered a problem that has not been solved in the prior art, namely the inability of the prior art to establish a three-dimensional field relative to a target tissue. Applicant contends that the remedy of the problem is not obvious unless the problem has been identified.

Eggers does not identify a problem in the prior art as being the inability to establish a three-dimensional field within the target tissue. As such, Applicant contends that the remedy of the problem is only obvious once the source of the problem has been identified by the Applicant in the Background of the Invention.

For the reasons presented above, Applicant contends that independent claims 1 and 12 are patentable over Eggers, as modified by Eggers, because the Office has failed to establish a *prima facie* case of obviousness. More particularly, the Office has failed to establish that it would have been an obvious matter of design choice to modify Eggers et al. with an additional electrode and insulating layer to obtain the invention because the Office has failed to consider the discovery of

the problem in the obviousness determination. The Office has failed to show that the problem of the prior art identified in the present invention had been previously identified anywhere in the prior art (*In re Zurko*, 111 F. 3d 887, 42 USPQ 2d 1476, 1479 (Fed. Cir.).

Applicant requests that the rejection of claims 1 and 12 be withdrawn.

Claims 2-11 are dependent upon claim 1, which has been shown to be allowable, and are therefore allowable as a matter of law.

Claims 13 and 14 have been canceled.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,

SMITH & HOPEN



By: _____

Molly L. Sauter
Reg No.: 46,457
180 Pine Avenue North
Oldsmar, FL 34677
(813) 925-8505
Agent for Applicants

Dated: April 6, 2009

CERTIFICATE OF ELECTRONIC TRANSMISSION
(37 C.F.R. 1.8 (a))

I HEREBY CERTIFY that this correspondence is being electronically transmitted to the Patent and Trademark Office through EFS Web on April 6, 2009.

Date: April 6, 2009

/jessica powell/

Jessica Powell